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EXAMINER	
BADIO, BARBARA P	
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Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

1. The reply filed on August 16, 2004 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s): Identification of a group of compounds in accordance with the exemplified groups or which are so similar within the same inventive concept and reduction to practice. See 37 CFR 1.111. Since the above-mentioned reply appears to be *bona fide*, applicant is given **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

2. The examiner notes applicant's comments in regards to Groups III and IV and Groups VII and VIII. The examiner notes the typographical error in Groups III and VII, i.e., M should read as "-CH_2**O**C(O)-" and not "-CH_2**CH_2**C(O)-". For this reason, the restriction is restated below.

Election/Restrictions

3. Due to the numerous variables in the claims, e.g., R^1, R^2, R^6, X, Z, Q^x, $Q^{x'}$, G, M, I, J, D, K, R^{40}, I', J', D', K', $R^{40'}$, etc. and their widely divergent meanings, this application discloses and claims a plurality of patentably independent and distinct inventions far too numerous to list individually. For this reason, restriction to one of the following Groups is required under 35 USC 121, wherein a Group is a set of patentably distinct invention, i.e., compounds. The following groups are **exemplary**:

Group I. Claims 1, 3, 4, 6, 8, 9 and 23 (in part), drawn to compounds and compositions thereof wherein $\mathbf{R^1}$ and $\mathbf{R^2}$ are independently hydrogen or hydroxy, **X** is hydroxy, **Z** is –M-$Q^{x'}$ wherein **M** is -$CH_2OC(O)$-, $\mathbf{Q^{x'}}$ is $I'_{i'}$-$J'_{j'}$-D'-$K'_{k'}$-$R^{40'}$ wherein **I'** is $[NR^{50'}\text{-}(CR^{51'}R^{52'})_{a'}\text{-}(CR^{53'}R^{54'})_{b'}\text{-}C(O)]$, **J'** is $[NR^{55'}\text{-}(CR^{56'}R^{57'})_{c'}\text{-}(CR^{58'}R^{59'})_{d'}\text{-}C(O)]$, **K'** is $[NR^{60'}\text{-}(CR^{61'}R^{62'})_{e'}\text{-}(CR^{63'}R^{64'})_{f'}\text{-}C(O)]$, $\mathbf{R^{40'}}$ is hydroxy, **D** is a penicillin (i.e., a compound having 4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid moiety as defined by the present specification), $\mathbf{R^{50'\text{-}64'}}$ each represent a hydrogen atom, **a'**, **c'**, **e'** and **I'** each is 1 and **b'**, **d'**, **f'**, **j'** and **k'** are each 0, classified in 540, subclass 2+.

Group II. Claims 1, 3, 4, 6, 8, 9 and 23 (in part), drawn to compounds and composition thereof wherein $\mathbf{R^1}$ and $\mathbf{R^2}$ are independently hydrogen or hydroxy, **X** is hydroxy, **Z** is –M-$Q^{x'}$ wherein **M** is -$CH_2CH_2C(O)$-, $\mathbf{Q^{x'}}$ is $I'_{i'}$-$J'_{j'}$-D'-$K'_{k'}$-$R^{40'}$ wherein **I'** is $[NR^{50'}\text{-}(CR^{51'}R^{52'})_{a'}\text{-}(CR^{53'}R^{54'})_{b'}\text{-}C(O)]$, **J'** is $[NR^{55'}\text{-}(CR^{56'}R^{57'})_{c'}\text{-}(CR^{58'}R^{59'})_{d'}\text{-}C(O)]$, **K'** is $[NR^{60'}\text{-}(CR^{61'}R^{62'})_{e'}\text{-}(CR^{63'}R^{64'})_{f'}\text{-}C(O)]$, $\mathbf{R^{40'}}$ is hydroxy, **D** is a penicillin (i.e., a compound having 4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid moiety as defined by the present specification), $\mathbf{R^{50'\text{-}64'}}$ each represent a hydrogen atom, **a'**, **c'**, **e'** and **I'** each is 1 and **b'**, **d'**, **f'**, **j'** and **k'** are each 0, classified in 540, subclass 2+.

Group III. Claims 1, 3, 4, 6, 8, 9 and 23 (in part), drawn to compounds and composition thereof wherein $\mathbf{R^1}$ and $\mathbf{R^2}$ are independently hydrogen or hydroxy, **X** is hydroxy, **Z** is –M-$Q^{x'}$ wherein **M** is -$CH_2OC(O)$-, $\mathbf{Q^{x'}}$ is $I'_{i'}$-$J'_{j'}$-D'-$K'_{k'}$-$R^{40'}$ wherein **I'** is $[NR^{50'}\text{-}(CR^{51'}R^{52'})_{a'}\text{-}(CR^{53'}R^{54'})_{b'}\text{-}C(O)]$, **J'** is $[NR^{55'}\text{-}(CR^{56'}R^{57'})_{c'}\text{-}(CR^{58'}R^{59'})_{d'}\text{-}C(O)]$, **K'** is $[NR^{60'}\text{-}(CR^{61'}R^{62'})_{e'}\text{-}(CR^{63'}R^{64'})_{f'}\text{-}C(O)]$, $\mathbf{R^{40'}}$ is hydroxy, **D** is a penicillin (i.e., a compound having 4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid moiety as defined by the

present specification), $R^{50'}$, $R^{55'}$ and $R^{60'}$ each represent a hydrogen atom, $R^{51'}$, $R^{52'}$, $R^{53'}$, $R^{54'}$, $R^{56'}$, $R^{57'}$, $R^{58'}$, $R^{59'}$, $R^{61'}$ $R^{62'}$, $R^{63'}$ and $R^{64'}$ each represent alkyl, substituted alkyl, alkenyl, substituted alkenyl, alkynyl or substituted alkynyl, **a'**, **c'**, **e'** and **l'** each is 1 and **b'**, **d'**, **f'**, **j'** and **k'** are each 0, classified in 540, subclass 2+.

Group IV. Claims 1, 3, 4, 6, 8, 9 and 23 (in part), drawn to compounds and composition thereof wherein R^1 and R^2 are independently hydrogen or hydroxy, **X** is hydroxy, **Z** is –M-$Q^{x'}$ wherein **M** is -$CH_2CH_2C(O)$-, $Q^{x'}$ is $l'_{i'}$-$J'_{j'}$-D'-$K'_{k'}$-$R^{40'}$ wherein **l'** is [$NR^{50'}$-($CR^{51'}R^{52'}$)$_{a'}$-($CR^{53'}R^{54'}$)$_{b'}$-C(O)], **J'** is [$NR^{55'}$-($CR^{56'}R^{57'}$)$_{c'}$-($CR^{58'}R^{59'}$)$_{d'}$-C(O)], **K'** is [$NR^{60'}$-($CR^{61'}R^{62'}$)$_{e'}$-($CR^{63'}R^{64'}$)$_{f'}$-C(O)], $R^{40'}$ is hydroxy, **D** is a penicillin (i.e., a compound having 4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid moiety as defined by the present specification), $R^{50'}$, $R^{55'}$ and $R^{60'}$ each represent a hydrogen atom, $R^{51'}$, $R^{52'}$, $R^{53'}$, $R^{54'}$, $R^{56'}$, $R^{57'}$, $R^{58'}$, $R^{59'}$, $R^{61'}$ $R^{62'}$, $R^{63'}$ and $R^{64'}$ each represent alkyl, substituted alkyl, alkenyl, substituted alkenyl, alkynyl or substituted alkynyl, **a'**, **c'**, **e'** and **l'** each is 1 and **b'**, **d'**, **f'**, **j'** and **k'** are each 0, classified in 540, subclass 2+.

Group V. Claims 1, 3, 4, 6, 8, 9 and 23 (in part), drawn to compounds and composition thereof wherein R^1 and R^2 are independently hydrogen or hydroxy, **X** is hydroxy, **Z** is –M-$Q^{x'}$ wherein **M** is -$CH_2OC(O)$-, $Q^{x'}$ is $l'_{i'}$-$J'_{j'}$-D'-$K'_{k'}$-$R^{40'}$ wherein **l'** is [$NR^{50'}$-($CR^{51'}R^{52'}$)$_{a'}$-($CR^{53'}R^{54'}$)$_{b'}$-C(O)], **J'** is [$NR^{55'}$-($CR^{56'}R^{57'}$)$_{c'}$-($CR^{58'}R^{59'}$)$_{d'}$-C(O)], **K'** is [$NR^{60'}$-($CR^{61'}R^{62'}$)$_{e'}$-($CR^{63'}R^{64'}$)$_{f'}$-C(O)], $R^{40'}$ is hydroxy, **D** is a cephalosporin (i.e., a compound having 5-thia-1-azabicyclo[4.2.0]oct-2-carboxylic acid moiety as defined by the present specification), $R^{50'-64'}$ each represent a hydrogen atom, **a'**, **c'**, **e'** and **l'** each is 1 and **b'**, **d'**, **f'**, **j'** and **k'** are each 0, classified in 540, subclass 2+.

Group VI. Claims 1, 3, 4, 6, 8, 9 and 23 (in part), drawn to compounds and composition thereof wherein $\mathbf{R^1}$ and $\mathbf{R^2}$ are independently hydrogen or hydroxy, **X** is hydroxy, **Z** is –M-$Q^{x'}$ wherein **M** is -$CH_2CH_2C(O)$-, $\mathbf{Q^{x'}}$ is $l'_{i'}$-$J'_{j'}$-D'-$K'_{k'}$-$R^{40'}$ wherein **l'** is [$NR^{50'}$-($CR^{51'}R^{52'})_{a'}$-($CR^{53'}R^{54'})_{b'}$-C(O)], **J'** is [$NR^{55'}$-($CR^{56'}R^{57'})_{c'}$-($CR^{58'}R^{59'})_{d'}$-C(O)], **K'** is [$NR^{60'}$-($CR^{61'}R^{62'})_{e'}$-($CR^{63'}R^{64'})_{f'}$-C(O)], $\mathbf{R^{40'}}$ is hydroxy, **D** is a cephalosporin (i.e., a compound having 5-thia-1-azabicyclo[4.2.0]oct-2-carboxylic acid moiety as defined by the present specification), $\mathbf{R^{50'\text{-}64'}}$ each represent a hydrogen atom, **a'**, **c'**, **e'** and **l'** each is 1 and **b'**, **d'**, **f'**, **j'** and **k'** are each 0, classified in 540, subclass 2+.

Group VII. Claims 1, 3, 4, 6, 8, 9 and 23 (in part), drawn to compounds and composition thereof wherein $\mathbf{R^1}$ and $\mathbf{R^2}$ are independently hydrogen or hydroxy, **X** is hydroxy, **Z** is –M-$Q^{x'}$ wherein **M** is -$CH_2OC(O)$-, $\mathbf{Q^{x'}}$ is $l'_{i'}$-$J'_{j'}$-D'-$K'_{k'}$-$R^{40'}$ wherein **l'** is [$NR^{50'}$-($CR^{51'}R^{52'})_{a'}$-($CR^{53'}R^{54'})_{b'}$-C(O)], **J'** is [$NR^{55'}$-($CR^{56'}R^{57'})_{c'}$-($CR^{58'}R^{59'})_{d'}$-C(O)], **K'** is [$NR^{60'}$-($CR^{61'}R^{62'})_{e'}$-($CR^{63'}R^{64'})_{f'}$-C(O)], $\mathbf{R^{40'}}$ is hydroxy, **D** is a cephalosporin (i.e., a compound having 5-thia-1-azabicyclo[4.2.0]oct-2-carboxylic acid moiety as defined by the present specification), $\mathbf{R^{50'}}$, $\mathbf{R^{55'}}$ **and** $\mathbf{R^{60'}}$ each represent a hydrogen atom, $\mathbf{R^{51'}}$, $\mathbf{R^{52'}}$, $\mathbf{R^{53'}}$, $\mathbf{R^{54'}}$, $\mathbf{R^{56'}}$, $\mathbf{R^{57'}}$, $\mathbf{R^{58'}}$, $\mathbf{R^{59'}}$, $\mathbf{R^{61'}}$ $\mathbf{R^{62'}}$, $\mathbf{R^{63'}}$ **and** $\mathbf{R^{64'}}$ each represent alkyl, substituted alkyl, alkenyl, substituted alkenyl, alkynyl or substituted alkynyl, **a'**, **c'**, **e'** and **l'** each is 1 and **b'**, **d'**, **f'**, **j'** and **k'** are each 0, classified in 540, subclass 2+.

Group VIII. Claims 1, 3, 4, 6, 8, 9 and 23 (in part), drawn to compounds and composition thereof wherein $\mathbf{R^1}$ and $\mathbf{R^2}$ are independently hydrogen or hydroxy, **X** is hydroxy, **Z** is –M-$Q^{x'}$ wherein **M** is -$CH_2CH_2C(O)$-, $\mathbf{Q^{x'}}$ is $l'_{i'}$-$J'_{j'}$-D'-$K'_{k'}$-$R^{40'}$ wherein **l'** is [$NR^{50'}$-($CR^{51'}R^{52'})_{a'}$-($CR^{53'}R^{54'})_{b'}$-C(O)], **J'** is [$NR^{55'}$-($CR^{56'}R^{57'})_{c'}$-($CR^{58'}R^{59'})_{d'}$-C(O)], **K'** is

$[NR^{60'}\text{-}(CR^{61'}R^{62'})_{e'}\text{-}(CR^{63'}R^{64'})_{f'}\text{-}C(O)]$, $R^{40'}$ is hydroxy, **D** is a cephalosporin (i.e., a compound having 5-thia-1-azabicyclo[4.2.0]oct-2-carboxylic acid moiety as defined by the present specification), $R^{50'}$, $R^{55'}$ and $R^{60'}$ each represent a hydrogen atom, $R^{51'}$, $R^{52'}$, $R^{53'}$, $R^{54'}$, $R^{56'}$, $R^{57'}$, $R^{58'}$, $R^{59'}$, $R^{61'}$ $R^{62'}$, $R^{63'}$ and $R^{64'}$ each represent alkyl, substituted alkyl, alkenyl, substituted alkenyl, alkynyl or substituted alkynyl, **a'**, **c'**, **e'** and **l'** each is 1 and **b'**, **d'**, **f'**, **j'** and **k'** are each 0, classified in 540, subclass 2+.

4. In accordance with the decisions in ***In re Harnisch***, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and ***Ex parte Hozumi***, 3 USPQ2d 1059 (bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 U.S.C. 103.

5. In the instant case, upon election of a single compound (or set of compounds), the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope

of the claim which fall into the same class and subclass as the elected compound (or set of compounds), but may also include additional compounds which fall in related subclasses. Examination will then proceed on the elected compounds AND the entire scope of the invention encompassing the elected compound as defined by common classification. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits. Note that the restriction requirement will not be made final until such time as applicant is informed of the full scope of compounds along with process of using said compound under examination. This will be set forth by reference to specific class(es) and subclass(es) examined. Should applicant traverse on the ground that the compounds are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission **will** be used in a rejection under 35 U.S. C. 103(a) of the others.

All compounds falling outside the scope of the elected Group will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications.

6. Applicant is reminded that upon cancellation of claims to non-elected invention, the inventors must be amended in compliance with 37 C.F.R. 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.17(i).

7. If desired, upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can **set forth** a group of compounds which are so similar within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

8. Rationale Establishing Patentable Distinctiveness Within Each Group

Each Invention Set listed above is directed to or involves compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over either of the other inventions, i.e. they are patentable over each other. Chemical structures which are similar are presumed to function similarly, whereas chemical structures that are not

similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrebuttable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holdings of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

The above Groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:

Each of the different Group is unrelated because each is drawn to structurally different compounds.

In addition, because of the numerous variables defined by the instant claims and definitions thereof, a serious burden is imposed on the examiner to perform a complete search of the entire scope of instant claims. Therefore, because of the reason given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

9. With the election of a Inventive Group, applicant is required to elect a specific species from under said Group for search purposes.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Other Matters

11. According to applicant, the structure of D' is not the inventive aspect of the compound but rather the portion of the compounds up to D'. However, the structure of D' is important to the structure of the claimed compounds and, thus, would be important to the search and classification of the compounds.

Telephone Inquiry

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
November 16, 2004